

1. Identification

Product identifier	PAXIL TABLETS
Other means of identification	Not available.
Synonym(s)	AROXAT 20 MG TABLETS * DEROXAT 20 MG TABLETS * NDC NO. 0029-3210-13 * NDC NO. 0029-3211-13 * NDC NO. 0029-3211-21 * NDC NO. 0029-3211-59 * NDC NO. 0029-3212-13 * NDC NO. 0029-3213-13 * PAXIL 10 MG TABLETS * PAXIL 20 MG TABLETS * PAXIL 30 MG TABLETS * PAXIL 40 MG TABLETS * AROPAX 20 MG TABLETS * AROPAX 30 MG TABLETS * TAGONIS 20 MG TABLETS * SEROXAT TABLETS * PAXIL DC * PAROXETINE HYDROCHLORIDE, FORMULATED PRODUCT
Recommended use	Medicinal Product This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Recommended restrictions	No other uses are advised.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
CALCIUM PHOSPHATE, DIBASIC	PHOSPHORIC ACID, CALCIUM SALT (1:1) CALCIUM ACID PHOSPHATE CALCIUM DIBASIC PHOSPHATE CALCIUM HYDROGEN ORTHOPHOSPHATE CALCIUM HYDROGEN PHOSPHATE CALCIUM MONOHYDROGEN PHOSPHATE CALCIUM ORTHOPHOSPHATE (CAHPO4) CALCIUM PHOSPHATE (CAHPO4) CALCIUM PHOSPHATE (1:1) CALCIUM PHOSPHATE (CA2(HPO4)2) CALCIUM SECONDARY PHOSPHATE DIBASIC CALCIUM PHOSPHATE DICALCIUM ORTHOPHOSPHATE DICALCIUM PHOSPHATE MONOCALCIUM ACID PHOSPHATE MONOCALCIUM ORTHOPHOSPHATE CALCIUM PHOSPHATE CAHO4P OHS04063 CALCIUMHYDROGENORTHOPHOSPHAT, MIT EINEM GEHALT AN FLUOR VON WENIGER ALS 0,005 GHT, BEZOGEN AUF DEN WASSERFREIEN STOFF	7757-93-9	80 - < 90
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	(-)-TRANS-4-(4-FLUOROPHENYL)-3-(3,4-METHYLENEDIOXY)PHENYL HYDROCHLORIDE HEMIHYDRATE BRL-29060A	110429-35-1	5 - < 10
MAGNESIUM STEARATE	OCTADECANOIC ACID, MAGNESIUM SALT STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE OCTADECANOIC ACID MAGNESIUM SALT MAGNESIUM OCTADECANOATE C36H70MGO4 OHS13505 RTECS WI4390000 MAGNESIUMDISTEARAT	557-04-0	1 - < 3
TITANIUM DIOXIDE	ANATASE BROOKITE RUTILE TITANIUM OXIDE TITANIUM DIOXIDE (TiO2) C.I. PIGMENT WHITE 6 C.I. 77891 TITANIUM(IV) OXIDE TITANIUM(4+) OXIDE TITANIUM PEROXIDE (TiO2) TITANIA (TiO2) PIGMENT WHITE 6 TITANIA KRONOS TITANIC OXIDE O2Ti OHS23510 RTECS XR2275000 DIOXIDO DE TITANIO TITANOKSID	13463-67-7	< 1
Other components below reportable levels			3 - < 5

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhoea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
General information	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	In the event of fire, cool tanks with water spray.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.
Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)	OHC	1	
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)	8 HR TWA	40 mcg/m3	
	OHC	3	REPRODUCTIVE HAZARD

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Use tight fitting goggles if dust is generated. Eye wash fountains are required.
Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	Wear appropriate chemical resistant clothing.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.

Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	May be harmful if swallowed.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	May be irritating to the skin.
Eye contact	Irritation can occur following direct contact with this material. Risk of serious damage to eyes.

Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhoea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.
---	---

Information on toxicological effects

Acute toxicity	May be harmful if swallowed. May irritate eyes and skin.
-----------------------	--

Components	Species	Test Results
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 7940 mg/kg
<i>Oral</i>		
LD50	Rat	> 10 g/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)		
Acute		
<i>Oral</i>		
LD50	Rat	374 mg/kg
Chronic		
<i>Oral</i>		
NOAEL	Monkey	3.5 mg/kg/day, 52 weeks
	Rat	5 mg/kg/day, 52 weeks
TD	Monkey	6 mg/kg/day, 52 weeks
	Rat	25 mg/kg/day, 52 weeks
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
Chronic		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m3, 1 years, TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years, Highest dose 5 mg/m3, 24 months
Subacute		
<i>Inhalation</i>		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks, Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.

Components	Species	Test Results
NOAEC	Guinea pig	26 mg/m3, 3 weeks, No evidence of significant inflammation in respiratory tract.
<i>Oral</i> NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.
Subchronic <i>Inhalation</i> LOEC	Rat	3.2 - 20 mg/m3, 8 min, Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Acute dermal irritation; OECD 404, Primary Irritation Index: 0 Result: Non-irritating to intact skin Species: Rabbit Acute dermal irritation; OECD 404, Primary Irritation Index: 3 Result: Irritating to damaged skin. Species: Rabbit
TITANIUM DIOXIDE	Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE	0
--------------------	---

Serious eye damage/eye irritation

Eye

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	OECD 405, Kay and Calndra - Grade 8. Result: Very severe irritant Species: Rabbit
TITANIUM DIOXIDE	OECD 405, Literature data Result: Mild irritant Species: Rabbit

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days
--------------------	------------------------------

Respiratory sensitization Not available.

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization

TITANIUM DIOXIDE	5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	OECD 406, 0 % Response rate. Result: Negative Species: Guinea pig
TITANIUM DIOXIDE	Patch test, Literature data Result: Negative Species: Human

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Ames - Screen Result: Negative
TITANIUM DIOXIDE	Ames, Literature data Result: Negative
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Chromosomal Aberration Assay In Vitro Result: Negative GreenScreen mammalian cell mutation assay Result: Negative

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	L5178Y mouse lymphoma thymidine kinase locus assay, GLP Result: Negative
TITANIUM DIOXIDE	Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data Result: Positive
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Micronucleus Assay, GLP Result: Negative Species: Mouse Mutation in Drosophila melanogaster Result: Negative Sister Chromatid Exchange Result: Negative
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: Negative
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Unscheduled DNA Synthesis, in vivo - in vitro Result: Negative Species: Rat
TITANIUM DIOXIDE	WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive

Carcinogenicity

Titanium dioxide is listed as a carcinogen by external agencies. Carcinogenic activity was seen in inhalation studies using laboratory animals. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: Negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: Negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months 25000 - 50000 ppm, Dietary study Result: Negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: Negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months Result: Negative Species: Mouse Test Duration: 18 months Result: Negative Species: Rat Test Duration: 2 years
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	

IARC Monographs. Overall Evaluation of Carcinogenicity

TITANIUM DIOXIDE (CAS 13463-67-7)	2B Possibly carcinogenic to humans.
-----------------------------------	-------------------------------------

Reproductive toxicity

Epidemiology studies have identified the ingredient paroxetine hydrochloride hemihydrate as a possible cause of developmental toxicity in humans.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	13 mg/kg/day Fertility, Female Result: Maternal toxicity; adverse effects on offspring. Species: Rat 13 mg/kg/day Fertility, Male Result: Parental toxicity, no adverse effects on fertility. Species: Rat 3 mg/kg/day Embryo-foetal development Result: Maternal NOAEL Species: Rabbit 4.3 mg/kg/day Fertility, Female Result: NOAEL Species: Rat
--------------------------------------	---

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

5 mg/kg/day Embryo-foetal development
Result: NOAEL
Species: Rat
6 mg/kg/day Embryofetal Development
Result: Maternal toxicity; Foetal NOAEL
Species: Rabbit
≥ 50 mg/kg/day Embryo-foetal development
Result: Maternal toxicity; adverse foetal effects
Species: Rat
Embryo-foetal development, Possible association with clinical use reported in epidemiology studies.
Species: Human
Organ: Cardiovascular malformations
Fertility, Male, Possible association with clinical use reported in epidemiology studies.
Result: Reversible effects on sperm quality.
Species: Human

Specific target organ toxicity - single exposure Central nervous system.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

Organ: Central Nervous System.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

Epidemiology
Organ: Bone; Testes (reversible).

Aspiration hazard Not likely, due to the form of the product.

Chronic effects Prolonged exposure may cause chronic effects.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components	Species		Test Results
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	25 mg/L, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	2.5 mg/L, 48 hours, Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	0.49 mg/L, 48 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1.6 mg/L, 96 hours, Static test, OECD 203
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	0.18 mg/L, 96 hours, Static test
Microtox	EC50	Microtox	8.2 mg/L, 15 minutes
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	0.5 mg/l, 7 days, Static renewal test, EPA 2002
	NOEC	Water flea (Ceriodaphnia dubia)	0.25 mg/L, 7 days
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Static test

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 2.4 Hours Measured, Deionized Water

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 292 nm, pH 5-9

Hydrolysis

Half-life (Hydrolysis-neutral)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE > 1 Years Measured, Deionized Water

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 1.3

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 2.94 Measured

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 0.8 Estimated

Mobility in general

Volatility

Henry's law

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 0 atm m3/mol Calculated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
--------------------------	--

SARA 302 Extremely hazardous substance	No
---	----

SARA 311/312 Hazardous chemical	No
--	----

NFPA ratings	Health: 3 Flammability: 1 Instability: 0
---------------------	--

HMIS® ratings	Health: 3* Flammability: 1 Physical hazard: 0
----------------------	---

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
---------------------------------------	----------------

Food and Drug Administration (FDA)	Not regulated.
---	----------------

US state regulations**US. Massachusetts RTK - Substance List**

TITANIUM DIOXIDE (CAS 13463-67-7)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No
*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).		

16. Other information, including date of preparation or last revision

Issue date	11-25-2013
Revision date	11-25-2013
Version #	18
Further information	Not available.
HMIS® ratings	Health: 3* Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 3 Flammability: 1 Instability: 0
References	GSK Hazard Determination
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Revision Information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Ecological Information: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection GHS: Classification